

K960866

Company Name, Address, and Telephone Number

Lake Region Manufacturing, Inc., (LRM)
340 Lake Hazeltine Drive
Chaska, MN 55318

APR - 5 1996

APR 3 10 18 AM '96

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Device Trade Name/Proprietary Name

LRM produces guidewires on an OEM basis for other manufacturers, kit assemblers, and distributors. Consequently there are a large number of trade and proprietary names not including or associated with LRM. LRM has no proprietary names of its own to be included with this submission.

Device Common Names/Unusual Names, and Classification Names

These devices are commonly known as guides, guidewires, or spring guidewires.

The "Intended Use" of the polymer/hydrophilic coated guidewire is to facilitate the placement of catheters or other non-vascular devices during gastroenterology and urology procedures.

The current classification name is Gastroenterology and Urology Catheter Accessory (78KOD).

LRM Establishment Registration Number: 2126666

Classification of Devices

The classification name listed above was originally classified as a Class II device by the Gastroenterology-Urology Review Panel (21 CFR 876.5130)

Applicability of Performance Standards

LRM has determined that no mandatory performance standards have been established for these devices under Section 514 of the Medical Device Amendments to Federal Food, Drug, and Cosmetic Act or by any subsequent regulatory action. LRM has also determined that there are no applicable voluntary standards.